Section 5: 510k) Summary

Applicant	Lepu Medical Technology (Beijing) Co., Ltd. No. 37 Chaoqian Road Changping District, Beijing 102200 P.R. China
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Contact:	Arthur Goddard 216-233-5722 asjgoddard@aol.com
Date	November 6, 2012
Name	Hoper™ PTCA Balloon Dilatation Catheter
Common Name:	PTCA Catheter
Classification Name:	Catheters, Transluminal Coronary Angioplasty, Percutaneous
Classification	21 CFR 870.5100
Product Code:	LOX
Predicate:	Empira™ Rx PTCA Dilatation Catheter, Creganna Tactx Medical, Inc. (K110133), FireStar® PTCA Dilatation Catheter, Cordis – Johnson & Johnson, (P880003), and FX miniRAIL™ RX PTCA Catheter (P020037).
Description:	Hoper Rapid Exchange (LPRX) Balloon Dilatation Catheter is a Percutaneous Transluminal Coronary Angioplasty (PTCA) Rapid Exchange System. The proximal shaft is a polymer coated stainless steel tube. The steel construction is designed to optimize proximal pushability with a smooth transition to a distal shaft specifically designed to be highly trackable. The semi-compliant balloon material allows dilatation with precise control of balloon diameter and length. Two radiopaque platinum marker bands are located within the balloon segment. The catheter is compatible with 5F or larger guiding catheters. The internal lumen of the catheter accepts a standard 0.014 inch PTCA guide wire. The proximal part of the guide wire enters the catheter's tip and advances coaxially out the catheter's proximal port, thereby allowing both coaxial guidance and rapid exchange of catheters with a single standard length guide wire. Two marked sections are located on the hypo tube shaft to indicate catheter position relative to the tip of either a brachial or femoral guiding catheter. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements. The product can be used to expand stenotic coronary vessel, and improve myocardial bleeding. This kind of balloon catheter possesses such merits as moderate compliance, high pressure resistance, minor diameter, etc.

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Specification **Balloon Diameter:** **Balloon Length:**	 1.5mm, 1.75mm, 2.0mm, 2.5mm, 2.75mm, 3.0mm, 3.5mm, and 4.0mm 9mm, 12mm, 14mm, 16mm, 18mm, 20mm, 24mm, 26mm, and 30mm
Intended Use	The balloon dilatation catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. This balloon dilatation catheter is not intended for the expansion or delivery of a stent.
Contraindication:	• Unprotected left main coronary artery. • Coronary artery spasm in the absence of significant stenosis. • In patients who are unable to receive anticoagulation therapy.
Warning	• For single patient use only. Do not re-sterilize as this can potentially result in compromised device performance, lead to device failure, increase risk of cross contamination, patient injury, illness and/ or death. • The product is sterile and non-pyrogenic. Do not use the catheter if its package has been opened or damaged. • To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis. • Do not subject catheter to more than four (4) rotation turns as this can potentially result in the catheter kinking and affect catheter performance. • To prevent possible damage to the balloon, do not remove the balloon protective jacket until ready to insert balloon catheter into the guiding catheter. • Purge the air and liquid in the balloon before operation. • Use only the recommended balloon inflation medium. To prevent the possibility of an air embolus, never use air or any gaseous medium to inflate the balloon. • PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk. • When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. • Do not advance or retract the catheter unless the balloon is fully deflated under vacuum as this can potentially result in damage to the vessel wall. • If resistance is met during manipulation, determine the cause of the resistance before proceeding. • Balloon pressure should not exceed the rated burst pressure indicated on the package label for each balloon model. The rated burst pressure is based on the results of in vitro testing. Use of a manual pressure monitoring device is recommended to prevent over pressurization. • After surgery, the balloon should be deflated before removing out from coronary artery.

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Warning continued	• PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication. • The product should be used only by physicians who have taken the training of percutaneous transluminal coronary angioplasty. .
Caution:	• Federal (USA) law restricts this device to sale by or on the order of a physician. • Read the Instructions for Use to understand the using method and performance of the product detailed before use, and ensure the effectiveness and safety. • Use the catheter prior to the "Use By" date (Expiration Date) specified on the package. • Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the procedure for which it is to be used. • The hydrophilic coating needs to be pre-wet to "activate" the coating for enhanced lubricity prior to use. • During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. After the procedure, anticoagulant therapy should be continued for a period of time as determined by the physician. • When using two guide wires, care should be taken when introducing, torqueing and removing one or both guide wires to avoid entanglement. It is recommended that one guide wire be completely withdrawn from the patient before removing any additional equipment. • Treat all disposable devices according to the local requirements for medical device waste disposal.
Adverse Effects:	Potential complications and adverse effects due to the use of this product include, but are not limited to, the following: • Death • Acute myocardial infraction • Total occlusion of the coronary artery or bypass graft coronary vessel dissection, perforation, rupture or injury • Restenosis of the dilated vessel • Hemorrhage or hematoma • Unstable angina • Arrhythmias, including ventricular fibrillation • Drug reactions, allergic reaction to contrast medium • Hypo/hypertension • Infection • Coronary artery spasm • Arteriovenous fistula • Embolism • Stroke • Cardiovascular accident • Transient ischemic attack • Myocardial ischemia • Pseudo aneurysm (at site of catheter insertion)

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Adverse Effects continue:	• Cardiac tamponade / pericardial effusion Renal failure • Coronary aneurysm • Vessel trauma requiring surgical repair or intervention • Cardiogenic shock • Coronary artery bypass graft surgery
Substantial Equivalency Information	Comparisons of the Hoper Balloon Dilatation Catheter and predicate devices demonstrated that the technological characteristics such as product performance, design, and intended use are substantially equivalent to the currently marketed predicate devices.
Performance Testing	The following *in vitro* performance tests were performed: • Dimensional verification • Balloon preparation, deployment, and retraction • Balloon rated burst pressure • Balloon fatigue • Balloon compliance (diameter vs. pressure) • Balloon inflation and deflation time • Catheter bond strength • Tip pull strength • Flexibility and kink • Torque strength • Radiopacity • Coating integrity • Particulate evaluation The following Biocompatibility tests were performed: • Cytotoxicity Study – ISO Elution Method • ISO Guinea Pig Maximum Sensitization Test • ISO Intracutaneous Study • ISO Systemic Toxicity Study • ASTM Hemolysis Study • *In vivo* Thromboresistance Study in the Dog, Jugular Vein • ASTM Partial Thromboplastin Time • USP Pyrogen Study – Material Mediated • C3a Complement Activation Assay • SC5b-9 Complement Activation Assay • Radiopacity • Coating integrity • Particulate evaluation The test results met all acceptance criterions, were similar to predicate devices, and ensured that the Hoper™ PTCA Balloon Dilatation Catheter design and construction are suitable for its intended use as recommended by the Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (FDA, September 8, 2010).
Conclusion	The information supports a determination of substantial equivalence between the Hoper™ PTCA Balloon Dilatation Catheter and the predicate devices described above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 13, 2013

Lepu Medical Technology (Beijing) Co., Ltd
% Arthur Goddard
FDA Regulatory and Quality Systems Consultant
1531 Felton Road
South Euclid, OH 44121-2722

Re: K123473
Trade/Device Name: Hoper™ PTCA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: June 17, 2013
Received: June 20, 2013

Dear Mr. Goddard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indication for Use Summary

510(k) Number (if known): K123473

Device Name: Hoper™ PTCA Balloon Dilatation Catheter

Indications For Use:

The balloon dilatation catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

This balloon dilatation catheter is not intended for the expansion or delivery of a stent.

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number 123473